

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Allen Comer et al.

Serial No.:

10/087,388

Group No.: Examiner:

1634 Switzer

Filed: Entitled:

03/01/02 Skin Substitutes For Irritancy Testing

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Dated: September 5, 2003

Sir or Madam:

Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

A check for \$180.00 is also enclosed pursuant to 37 C.F.R. § 1.17(p) for filing this Information Disclosure Statement after three months as set forth in 37 C.F.R. § 1.97(c).

The Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. 08-1290. An originally executed duplicate of this transmittal is enclosed for this purpose.

Dated: September 5, 2003

itchell Jones

Registration No. 44,174

09/15/2003 RBLANCO 00000003 10087388

02 FC:1806

180.00 OP

MEDLEN & CARROLL, LLP 101 Howard Street, Suite 350 San Francisco, California 94105

608/218-6900



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Allen Comer et al.

Serial No.:

10/087,388

Group No.:

1634

Filed:

03/01/02

Examiner:

Switzer

Entitled:

Skin Substitutes For Irritancy Testing

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: September 5, 2003

Bv

Mary Ellen Waite

Sir or Madam:

Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

A check for \$180.00 is also enclosed pursuant to 37 C.F.R. § 1.17(p) for filing this Information Disclosure Statement after three months as set forth in 37 C.F.R. § 1.97(c).

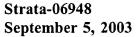
The Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. 08-1290. An originally executed duplicate of this transmittal is enclosed for this purpose.

Dated: September 5, 2003

J. Mitchell Jones

Registration No. 44,174

MEDLEN & CARROLL, LLP 101 Howard Street, Suite 350 San Francisco, California 94105 608/218-6900



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Allen Comer et al.

Serial No.:

10/087,388

03/01/02

Group No.: 1634 Examiner:

Switzer

Filed:

Entitled: Skin Substitutes For Irritancy Testing

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the United States Postal Service in an envelope as first class mail addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on September 5, 2003.

Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following printed publications are referred to in the body of the specification:

- U.S. Pat No. 6,074,859;
- U.S. Pat No. 5,968,546;

Strata-06948 September 5, 2003

- U.S. Pat No. 4,485,096;
- U.S. Pat No. 6,039,760;
- U.S. Pat No. 5,536,656;
- U.S. Pat No. 5,989,837;
- U.S. Pat No. 5,994,115;
- U.S. Pat No. 5,693,332;
- U.S. Pat No. 5,658,331;
- Sando et al., J. Biol. Chem., 271(36): 22044-51 (1996);
- Watanabe et al., J. Biol. Chem., 273(16): 9651-5 (1998);
- Ponec et al., J. Invest. Dermatol., 109(3): 348-55 (1997);
- Denda et al., J. Invest. Dermatol., 111(5): 858-63 (1998);
- Hanley et al., J. Clin. Invest., 100(3): p. 705-12 (1997);
- Hanley et al., J. Invest. Dermatol., 113(5): 788-95 (1999);
- Zhang et al., J. Biol. Chem., 273(28): 17917-25 (1998);
- Anderson and Young, Quantitative Filter Hybridization, in Nucleic Acid Hybridization [1985];
- Smith and Waterman, Adv. Appl. Math. 2: 482 (1981);
- Needleman and Wunsch, J. Mol. Biol. 48:443 (1970);
- Pearson and Lipman, Proc. Natl. Acad. Sci. (U.S.A.) 85:2444 (1988);
- Graham and van der Eb, Virol., 52:456 [1973];
- deWet et al., Mol. Cell. Biol. 7:725 [1987];
- Fuchs, J. Cell. Sci. Suppl., 17: 197-208 (1993);
- Schurer et al., Dermatologica, 183: 77-94 (1991);
- Aeschlimann et al., Thrombosis & Haemostasis, 71(4): 402-15 (1994);
- Reichert et al., The cornified envelope: a key structure of terminally

Strata-06948 September 5, 2003

- differentiating keratinocytes, in Molecular Biology of the Skin, M. Darmon, Editor. 1993, Academic Press, Inc.: San Diego. 107-150 (1993);
- Sachsenmeier et al., J. Biol. Chem., 271: 5-8 (1996);
- Hines et al., Promega Notes, 59: p. 30-36 (1996);
- Hines et al., J. Biol. Chem., 271(11): 6245-6251 (1996);
- Polakowska et al., Developmental Dynamics, 199(3): 176-88 (1994);
- Haake et al., J. Invest. Derm. Symp. Proc., 3: 28-35 (1998);
- Wertz et al., Chem. Phys. Lipids., 91(2): 85-96 (1998);
- Meana et al., Burns 24:621-30 (1998);
- Baden, In Vitro Cell. Dev. Biol. 23(3):205-213 (1987);
- Boucamp et al., J. cell. Boil. 106:761-771 (1988);
- Bell et al., Proc. Nat. Acad. Sci. USA, 76: 1274-1278 (1979);
- Fusenig, Epithelial-mesenchymal interactions regulate keratinocyte growth and differentiation in vitro, in The Keratinocyte Handbook, I.M. Leigh, Lane, E.B., and F.M. Watt, Editor. 1994, University Press: Cambridge (1994);
- Parenteau et al., Cytotechnology, 9: 163-171(1992);
- Cumpstone et al., J. Invest. Dermatol., 92(4): 598-600 (1989);
- Ponec, Int. J. Cosmetic Sci., 14: 245-264 (1992);
- Mak et al., J. Invest. Dermatol., 96(3): 323-7 (1991);
- Grubauer et al., J. Lipid Res., 30(3): 323-33 (1989);
- Ponec et al., J. Invest. Dermatol., 109(3): 348-55 (1997);
- Williams et al., J Investig. Dermatol. Symp. Proc., 3(2): 75-9 (1998).
- Vicanova et al., J. Investig. Dermatol. Symp. Proc., 3(2): 114-20 (1998);
- Aszterbaum et al., Pediatr. Res., 31(4 Pt 1): 308-17 (1992);
- Hardman et al., Development, 125: 1541-1552 (1998);
- Segre et al., Nat. Genet., 22(4): 356-60 (1999);

Strata-06948 September 5, 2003

- Zhang et al., J. Biol. Chem., 273(28): 17917-25 (1998);
- Stryer ed., Biochemistry, pg. 17-21, 2nd ed, WH Freeman and Co., 1981;
- Denyer et al., Drug Discov. Today 3:323-32 (1998);
- Gonzales et al., Drug. Discov. Today 4:431-39 (1999);
- Schroeder and Neagle, J. Biomol. Screening 1:75-80 (1996);
- de Brugerolle de Fraissinette et al., Cell Biology and Toxicology, 15:121 [1999];
- Mukaida et al., J. Immunology, 143:1366 [1989];
- Roebuck, J. Interferon Cytokine Res., 19:429 [1999];
- Iyer et al., Science 283:83 [1999];
- Fambrough et al., Cell 97:727 [1999];
- Eisen et al., PNAS 95:14863 [1998];
- Golub et al., Science 286:531 [1999];
- Myers et al., A. J. Surg. 170(1):75-83 (1995);
- Boyce et al., J. Invest. Dermatol., 107(1): p. 82-7 (1996);
- Shields et al., J. Biol. Chem, 271(33): 20009-17 (1996);
- Zhang et al., J. Biol. Chem., 273(28): 17917-25 (1998);
- Geiman et al., Nucleic Acids Res., 28(5): 1106-1113 (2000);
- Mahatan et al., Nucleic Acids Res., 27(23): 4562-9 (1999)).
- Carroll et al., Proc. Natl. Acad. Sci. USA, 90(21): p. 10270-4 (1993);
- Lee et al., J. Biol. Chem., 271(8): 4561-8 (1996);
- Yet et al., J. Biol. Chem., 273(2): 1026-31 (1998);
- Lopez-Bayghen et al., J. Biol. Chem., 271(1): 512-520 (1996);
- Perkins et al., Toxicological Sciences, 48:218 [1999];
- Furutani et al., Nuc. Acid Res. 14:3167 [1986];
- Mori and Prager, Blood 87:3410 [1996];

- Corsini et al., J. Invest Dermatol. 108:892 [1997];
- Elefanty et al., Proc Natl Acad Sci U S A, 95:11897 [1998];
- Morrison et al., Mech Dev, 1999. 84169 [1999];
- Behne et al., J. Invest. Dermatol., 114(1): 185-92 (2000);
- Asbill et al., Pharm. Research 17(9): 1092-97 (2000);
- Allen-Hoffmann et al., J. Invest. Dermatol., 114(3): 444-455 (2000);
- Chang et al., Am J. Respir Cell Mol Biol. 22:502 [2000];
- Abe et al., Am J. Respir Cell Mol Biol., 22:51 [2000];
- Geiman et al., Nucleic Acids Res., 28(5): 1106-1113 (2000);
- Jin et al., Biochem Biophys Res Commun, 270:978 [2000].

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: September 5, 2003

J. Mitchell Jones Reg. No. 44,174

MEDLEN & CARROLL, LLP 101 Howard Street, Suite 350 San Francisco, California 94105

(608) 218-6900

FORM PTO-1449 U.S. Department of Commerce Serial No.: 10/087,388 Attorney Docket No.: STRATA-06948 Patent and Trademark Office (Modified) INFORMATIO DISCLOSURE STATEMENT BY APPLICANT (Use Several Seve Applicant: Allen Comer et al. Filing Date: 03/01/02 Group Art Unit: (37 CFR § 1.98(b)) SEP. 1 2 2003 ä U.S. PATENT DOCUMENTS Cite Serial / Paten Examiner Issue Date Applicant / Patentee Class Subclass Filing Date Number Initials 6,074,859 435 189 7/9/98 1 6/13/00 Hirokawa et al. 2 5,968,546 10/19/99 Baur et al. 424 444 5/15/98 3 4,485,096 11/27/84 Bell 424 95 5/26/82 4 6,039,760 3/21/00 623 15 Eisenberg 2/16/96 5 Kemp et al. 240.23 5,536,656 7/16/96 435 2/9/94 6 435 5,989,837 11/23/99 Allen-Hoffmann et al. 7.21 7/13/98 7 5,994,115 11/30/99 435 235.1 7/22/97 Meyers 8 5,693,332 12/2/97 Hansbrough 424 426 8/11/95 9 8/19/97 6/7/95 5,658,331 623 15 Della Valle et al. FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS Translation Document Publication Date Country / Patent Office Class Subclass Number Yes No OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication) 10 Sando et al., J. Biol. Chem., 271(36): 22044-51 (1996) Watanabe et al., J. Biol. Chem., 273(16): 9651-5 (1998) 11 12 Ponec et al., J. Invest. Dermatol., 109(3): 348-55 (1997) 13 Denda et al., J. Invest. Dermatol., 111(5): 858-63 (1998) 14 Hanley et al., J. Clin. Invest., 100(3): p. 705-12 (1997) 15 Hanley et al., J. Invest. Dermatol., 113(5): 788-95 (1999) 16 Zhang et al., J. Biol. Chem., 273(28): 17917-25 (1998) 17 deWet et al., Mol. Cell. Biol. 7:725 [1987] 18 Smith and Waterman, Adv. Appl. Math. 2: 482 (1981) 19 Needleman and Wunsch, J. Mol. Biol. 48:443 (1970) 20 Pearson and Lipman, Proc. Natl. Acad. Sci. (U.S.A.) 85:2444 (1988) 21 Graham and van der Eb, Virol., 52:456 [1973] 22 Fuchs, J. Cell. Sci. Suppl., 17: 197-208 (1993) 23 Schurer et al., Dermatologica, 183: 77-94 (1991) 24 Aeschlimann et al., Thrombosis & Haemostasis, 71(4): 402-15 (1994) Reichert et al., The cornified envelope: a key structure of terminally differentiating keratinocytes, in Molecular Biology of the Skin, M. 25 Darmon, Editor. 1993, Academic Press, Inc.: San Diego. 107-150 (1993) 26 Sachsenmeier et al., J. Biol. Chem., 271: 5-8 (1996) 27 Hines et al., Promega Notes, 59: p. 30-36 (1996) 28 Anderson and Young, Quantitative Filter Hybridization, in Nucleic Acid Hybridization [1985] Examiner: Date Considered: EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Modified)

U.S. Department of Commerce Patent and Trademark Office

Attorney Docket No.: STRATA-06948

Applicant: Allen Comer et al.

Serial No.: 10/087,388

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)

(37 CFR § 39	98(b))	(Use Several Sneets II Necessary)	Filing Date: 03/01/02	Group Art Unit:
70		OTHER DOCUMENTS (Including Author, Title, Da	ate, Relevant Pages, Place of Publication)	
	29	Hines et al., J. Biol. Chem., 271(11): 6245-6251 (1996)		
	30	Polakowska et al., Developmental Dynamics, 199(3): 176-88 (1994)		
PADEMARKS	31	Haake et al., J. Invest. Derm. Symp. Proc., 3: 28-35 (1998)		
	32	Wertz et al., Chem. Phys. Lipids., 91(2): 85-96 (1998)		
	33	Meana et al., Burns 24:621-30 (1998)		
	34	Baden, In Vitro Cell. Dev. Biol. 23(3):205-213 (1987)		
	35	Boucamp et al., J. cell. Boil. 106:761-771 (1988)		
	36	Bell et al., Proc. Nat. Acad. Sci. USA, 76: 1274-1278 (1979)		
	37	Fusenig, Epithelial-mesenchymal interactions regulate keratinocyte growth and differentiation in vitro, in The Keratinocyte Handbook, I.M. Leigh, Lane, E.B., and F.M. Watt, Editor. 1994, University Press: Cambridge (1994)		
	38	Parenteau et al., Cytotechnology, 9: 163-171(1992)		
	39	Cumpstone et al., J. Invest. Dermatol., 92(4): 598-600 (1989)		
	40	Ponec, Int. J. Cosmetic Sci., 14: 245-264 (1992)		
	41	Mak et al., J. Invest. Dermatol., 96(3): 323-7 (1991)		
	42	Grubauer et al., J. Lipid Res., 30(3): 323-33 (1989)		
	43	Williams et al., J Investig. Dermatol. Symp. Proc., 3(2): 75-9 (1998)		
	44	Vicanova et al., J. Investig. Dermatol. Symp. Proc., 3(2): 114-20 (1998)		
	45	Aszterbaum et al., Pediatr. Res., 31(4 Pt 1): 308-17 (1992)		
	46	Hardman et al., Development, 125: 1541-1552 (1998)		
	47	Segre et al., Nat. Genet., 22(4): 356-60 (1999)		
	48	Stryer ed., Biochemistry, pg. 17-21, 2nd ed, WH Freeman and Co. (1981)		
	49	Denyer et al., Drug Discov. Today 3:323-32 (1998)		
	50	Gonzales et al., Drug. Discov. Today 4:431-39 (1999)		
	51	Schroeder and Neagle, J. Biomol. Screening 1:75-80 (1996)		
	52	Mukaida et al., J. Immunology, 143:1366 [1989]		
	53	Roebuck, J. Interferon Cytokine Res., 19:429 [1999]		
	54	Iyer et al., Science 283:83 [1999]		
	55	Fambrough et al., Cell 97:727 [1999]		
	56	Eisen et al., PNAS 95:14863 [1998]		
	57	de Brugerolle de Fraissinette et al., Cell Biology and Toxicology, 15:121 [1999]		
Examiner:			Date Considered:	

FORM PTO-1449 U.S. Department of Commerce Attorney Docket No.: STRATA-06948 Serial No.: 10/087,388 (Modified) Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT BY APPLICANT Applicant: Allen Comer et al. (Use Several Sheets If Necessary) Filing Date: 03/01/02 Group Art Unit: OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication) Golub et al., Science 286:531 [1999] Myers et al., A. J. Surg. 170(1):75-83 (1995) PADEMA 60 Boyce et al., J. Invest. Dermatol., 107(1): p. 82-7 (1996) 61 Shields et al., J. Biol. Chem, 271(33): 20009-17 (1996) 62 Geiman et al., Nucleic Acids Res., 28(5): 1106-1113 (2000) 63 Mahatan et al., Nucleic Acids Res., 27(23): 4562-9 (1999) 64 Carroll et al., Proc. Natl. Acad. Sci. USA, 90(21): p. 10270-4 (1993) 65 Lee et al., J. Biol. Chem., 271(8): 4561-8 (1996) 66 Yet et al., J. Biol. Chem., 273(2): 1026-31 (1998) 67 Lopez-Bayghen et al., J. Biol. Chem., 271(1): 512-520 (1996) 68 Perkins et al., Toxicological Sciences, 48:218 [1999] 69 Furutani et al., Nuc. Acid Res. 14:3167 [1986] 70 Mori and Prager, Blood 87:3410 [1996] 71 Corsini et al., J. Invest Dermatol. 108:892 [1997] 72 Elefanty et al., Proc Natl Acad Sci U S A, 95:11897 [1998]

Examiner:

Date Considered:

EXAMINER:

73

74

75

76

77

78

79

Morrison et al., Mech Dev, 1999. 84169 [1999]

Behne et al., J. Invest. Dermatol., 114(1): 185-92 (2000)

Chang et al., Am J. Respir Cell Mol Biol. 22:502 [2000]

Jin et al., Biochem Biophys Res Commun, 270:978 [2000]

Abe et al., Am J. Respir Cell Mol Biol., 22:51 [2000]

Allen-Hoffmann et al., J. Invest. Dermatol., 114(3): 444-455 (2000)

Asbill et al., Pharm. Research 17(9): 1092-97 (2000)

Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.